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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,676	10/16/2001	Eija Marjut Pirhonen	01942-00003	6631

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John P. Iwanicki
BANNER & WITCOFF, LTD.
28th Floor
28 State Street
Boston, MA 02109

EXAMINER

THOMPSON, CAMIE S

ART UNIT	PAPER NUMBER
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1774

DATE MAILED: 04/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,676

Applicant(s)

PIRHONEN, EIJA MARJUT

Examiner

Camie S Thompson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 38-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 29-36 is/are rejected.
- 7) ☐ Claim(s) 27, 28 and 37 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5&6. 6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I, claims 1-37 with traverse has been acknowledged. The argument that the product and method are so interrelated is not persuasive. The scaffold material can be made by another method. Further, the search required for each grouping is different.

Therefore, the requirement is still deemed proper and therefore is made **FINAL**.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1-8, 11-12, 15-20, 31-33 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al., U.S. Patent Number 4,655,777.

Dunn discloses a porous composite material comprising sintered bioactive glass fibers wherein the sintering temperature is from 600°C to 1150° for 1 hour as per instant claims 1-5 and 17 -18 (see column 2, lines 40-68 and column 4, lines 3-12). The reference also discloses that the fibers are encased in a matrix of a polymer such as poly(L-lactide) as per instant claims 6-8 (see

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reference claim 1). Dunn discloses that the bioactive glass fibers were cut in 2-inch lengths and have a diameter from .074 mm - .559 mm as per instant claims 15-16 and 19-20 (see column 8, lines 41-54). Column 11, lines 1-23 of the reference discloses that a poly(DL-lactide film can be attached to the composite material as per instant claims 31-33. Claims 3-5, 11-12 and 35-37 are product by process claims. Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process. See MPEP 2113.

4. Claims 1, 13-14, 29 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Ylanen et al., U.S. Patent Number 6,248,344.

Ylanen discloses a porous composite comprising sintered bioactive glass that promotes bone growth as per instant claims 1 and 34 (see abstract, column 3, lines 30-35 and column 4, lines 28-63). Additionally, the reference discloses that glass has the following composition:

Silicon dioxide	53-60%
Sodium oxide	0-34%
Potassium oxide	1-20%
Magnesium oxide	0-5%
Calcium oxide	5-25%
Boron oxide	0-4%
Phosphoric acid	0.5-6%

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Provided that sodium oxide and potassium oxide equal 16-35% by weight; potassium oxide and magnesium oxide equal 5-20% by weight and magnesium oxide and calcium oxide equal 10-25% by weight as per instant claims 13 and 14 (see column 5, lines 1-15). Ylanen also discloses that the compression strength of the composite is 17 MPa as per instant claim 29 (see Table 3).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 9-10 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al., U.S. Patent Number 4,655,777.

Dunn discloses a porous composite material comprising sintered bioactive glass fibers wherein the sintering temperature is from 600°C to 1150° for 1 hour as per instant claim 1 (see column 2, lines 40-68 and column 4, lines 3-12). Dunn does not disclose the thickness of the coating and the porosity of the composite material as per instant claim 9-10 and 21-22. The thickness of the coating protects the fibers. Discovery of optimum values of a result effective variable involves only routine skill in the art in re Boesch, 617 F.2. 272, 205 USPQ 215 (CCPA). Therefore, it would have been obvious to one of ordinary skill in the art to have a coating on the bioactive glass fibers from about 1 micron to 200microns in order to prevent breakage of the fibers. The bioactive fibers disclosed in the reference are highly porous as shown in column 2, lines 67-68.

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Therefore, it would be expected that the porosity of the composite comprising the bioactive fibers would be between 5 to 95 volume percent.

7. Claims 1, 6 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al., U.S. Patent Number 4,655,777 in view of Tormala et al., U.S. Patent Number 6,350,284.

Dunn discloses a porous composite material comprising sintered bioactive glass fibers wherein the sintering temperature is from 600°C to 1150° for 1 hour as per instant claim 1 (see column 2, lines 40-68 and column 4, lines 3-12). The reference also discloses that the fibers are encased in a matrix of a polymer such as poly(L-lactide) as per instant claim 6 (see reference claim 1). The Dunn reference does not disclose that the scaffold material is a carrier for bioactive agents as per instant claims 23-26. Tormala teaches a composite material comprising bioactive glass that enhances bone growth and has a favorable pore size. Additionally, the Tormala reference teaches that the composite material can be a carrier for bioactive agents such as growth hormones and antibiotics (see column 4, lines 48-62). The composite material is used with the bioactive agents to promote healing. Therefore, it would have been obvious to one of ordinary skill in the art to use the composite material of the Dunn reference with a bioactive agent such as an antibiotic in order to promote bone healing as shown in the Tormala reference in column 4, lines 48-62.

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8. Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Camie S. Thompson whose telephone number is (703) 305-4488. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cynthia H. Kelly, can be reached at (703) 308-0449. The fax phone numbers for the Group are (703) 872-9310 {before finals} and (703) 872-9311 {after finals}.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

CYNTHIA H. KELLY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

